

118TH CONGRESS  
1ST SESSION

# S. 142

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products.

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## IN THE SENATE OF THE UNITED STATES

JANUARY 30, 2023

Ms. KLOBUCHAR (for herself, Mr. GRASSLEY, Mr. DURBIN, Mr. CRAMER, Mr. BLUMENTHAL, Mr. KELLY, Mr. VAN HOLLEN, and Mr. BOOKER) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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## A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1   **SECTION 1. SHORT TITLE.**

2       This Act may be cited as the “Preserve Access to Af-  
3   fordable Generics and Biosimilars Act”.

4   **SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF  
5                   PURPOSES.**

6       (a) FINDINGS.—Congress finds the following:

7               (1) In 1984, the Drug Price Competition and  
8   Patent Term Restoration Act (Public Law 98–417)  
9   (referred to in this Act as the “1984 Act”), was en-  
10  acted with the intent of facilitating the early entry  
11  of generic drugs while preserving incentives for inno-  
12  vation.

13              (2) Prescription drugs make up approximately  
14   10 percent of the national health care spending.

15              (3) Initially, the 1984 Act was successful in fa-  
16  cilitating generic competition to the benefit of con-  
17  sumers and health care payers, although 88 percent  
18   of all prescriptions dispensed in the United States  
19   are generic drugs, they account for only 28 percent  
20   of all expenditures.

21              (4) Generic drugs cost substantially less than  
22   brand name drugs, with discounts off the brand  
23   price averaging 80 to 85 percent.

24              (5) Federal dollars currently account for over  
25   40 percent of the \$325,000,000,000 spent on retail

1       prescription drugs, and this share is expected to rise  
2       to 47 percent by 2025.

3                     (6)(A) In recent years, the intent of the 1984  
4       Act has been subverted by certain settlement agree-  
5       ments in which brand name companies transfer  
6       value to their potential generic competitors to settle  
7       claims that the generic company is infringing the  
8       branded company's patents.

9                     (B) These "reverse payment" settlement agree-  
10      ments—

11                         (i) allow a branded company to share its  
12       monopoly profits with the generic company as a  
13       way to protect the branded company's monop-  
14       oly; and

15                         (ii) have unduly delayed the marketing of  
16       low-cost generic drugs contrary to free competi-  
17       tion, the interests of consumers, and the prin-  
18       ciples underlying antitrust law.

19                     (C) Because of the price disparity between  
20       brand name and generic drugs, such agreements are  
21       more profitable for both the brand and generic man-  
22       ufacturers than competition and will become increas-  
23       ingly common unless prohibited.

1                   (D) These agreements result in consumers los-  
2                   ing the benefits that the 1984 Act was intended to  
3                   provide.

4                   (7) In 2010, the Biologics Price Competition  
5                   and Innovation Act (Public Law 111–148) (referred  
6                   to in this Act as the “BPCIA”), was enacted with  
7                   the intent of facilitating the early entry of biosimilar  
8                   and interchangeable follow-on versions of branded  
9                   biological products while preserving incentives for in-  
10                  novation.

11                  (8) Biological drugs play an important role in  
12                  treating many serious illnesses, from cancers to ge-  
13                  netic disorders. They are also expensive, rep-  
14                  resenting more than 40 percent of all prescription  
15                  drug spending.

16                  (9) Competition from biosimilar and inter-  
17                  changeable biological products promises to lower  
18                  drug costs and increase patient access to biological  
19                  medicines. But “reverse payment” settlement agree-  
20                  ments also threaten to delay the entry of biosimilar  
21                  and interchangeable biological products, which would  
22                  undermine the goals of BPCIA.

23                  (b) PURPOSES.—The purposes of this Act are—

24                  (1) to enhance competition in the pharma-  
25                  ceutical market by stopping anticompetitive agree-

ments between brand name and generic drug and biosimilar biological product manufacturers that limit, delay, or otherwise prevent competition from generic drugs and biosimilar biological products; and

## **8 SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.**

9           (a) IN GENERAL.—The Federal Trade Commission  
10 Act (15 U.S.C. 44 et seq.) is amended by inserting after  
11 section 26 (15 U.S.C. 57c–2) the following:

## 12 “SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS

## 13 AND BIOSIMILARS.

14           “(a) IN GENERAL.—

15       “(1) ENFORCEMENT PROCEEDING.—The Com-  
16       mission may initiate a proceeding to enforce the pro-  
17       visions of this section against the parties to any  
18       agreement resolving or settling, on a final or interim  
19       basis, a patent claim, in connection with the sale of  
20       a drug product or biological product.

**21                  "(2) PRESUMPTION AND VIOLATION.—**

22                 “(A) IN GENERAL.—Subject to subparagraph  
23                 graph (B), in such a proceeding, an agreement  
24                 shall be presumed to have anticompetitive ef-  
25                 fects and shall be a violation of this section if—

1                         “(i) an ANDA filer or a biosimilar bi-  
2                         ological product application filer receives  
3                         anything of value, including an exclusive li-  
4                         cense; and

5                         “(ii) the ANDA filer or biosimilar bio-  
6                         logical product application filer agrees to  
7                         limit or forgo research, development, man-  
8                         ufacturing, marketing, or sales of the  
9                         ANDA product or biosimilar biological  
10                         product, as applicable, for any period of  
11                         time.

12                         “(B) EXCEPTION.—Subparagraph (A)  
13                         shall not apply if the parties to such agreement  
14                         demonstrate by clear and convincing evidence  
15                         that—

16                         “(i) the value described in subpara-  
17                         graph (A)(i) is compensation solely for  
18                         other goods or services that the ANDA  
19                         filer or biosimilar biological product appli-  
20                         cation filer has promised to provide; or

21                         “(ii) the procompetitive benefits of the  
22                         agreement outweigh the anticompetitive ef-  
23                         fects of the agreement.

1       “(b) LIMITATIONS.—In determining whether the set-  
2 tling parties have met their burden under subsection  
3 (a)(2)(B), the fact finder shall not presume—

4           “(1) that entry would not have occurred until  
5 the expiration of the relevant patent or statutory ex-  
6 clusivity; or

7           “(2) that the agreement’s provision for entry of  
8 the ANDA product or biosimilar biological product  
9 prior to the expiration of the relevant patent or stat-  
10 utory exclusivity means that the agreement is pro-  
11 competitive.

12       “(c) EXCLUSIONS.—Nothing in this section shall pro-  
13 hibit a resolution or settlement of a patent infringement  
14 claim in which the consideration that the ANDA filer or  
15 biosimilar biological product application filer, respectively,  
16 receives as part of the resolution or settlement includes  
17 only one or more of the following:

18           “(1) The right to market and secure final ap-  
19 proval in the United States for the ANDA product  
20 or biosimilar biological product at a date, whether  
21 certain or contingent, prior to the expiration of—

22           “(A) any patent that is the basis for the  
23 patent infringement claim; or

24           “(B) any patent right or other statutory  
25 exclusivity that would prevent the marketing of

1           such ANDA product or biosimilar biological  
2           product.

3           “(2) A payment for reasonable litigation ex-  
4           penses not to exceed—

5                 “(A) for calendar year 2023, \$7,500,000;  
6                 or

7                 “(B) for calendar year 2024 and each sub-  
8                 sequent calendar year, the amount determined  
9                 for the preceding calendar year adjusted to re-  
10                flect the percentage increase (if any) in the  
11                Producer Price Index for Legal Services pub-  
12                lished by the Bureau of Labor Statistics of the  
13                Department of Labor for the most recent cal-  
14                endar year.

15           “(3) A covenant not to sue on any claim that  
16           the ANDA product or biosimilar biological product  
17           infringes a United States patent.

18           “(d) ENFORCEMENT.—

19           “(1) ENFORCEMENT.—A violation of this sec-  
20           tion shall be treated as an unfair method of competi-  
21           tion under section 5(a)(1).

22           “(2) JUDICIAL REVIEW.—

23                 “(A) IN GENERAL.—Any party that is sub-  
24                 ject to a final order of the Commission, issued  
25                 in an administrative adjudicative proceeding

1           under the authority of subsection (a)(1), may,  
2           within 30 days of the issuance of such order,  
3           petition for review of such order in—

4                  “(i) the United States Court of Ap-  
5                 peals for the District of Columbia Circuit;

6                  “(ii) the United States Court of Ap-  
7                 peals for the circuit in which the ultimate  
8                 parent entity, as defined in section  
9                 801.1(a)(3) of title 16, Code of Federal  
10                Regulations, or any successor thereto, of  
11                the NDA holder or biological product li-  
12                cense holder is incorporated as of the date  
13                that the NDA or biological product license  
14                application, as applicable, is filed with the  
15                Commissioner of Food and Drugs; or

16                  “(iii) the United States Court of Ap-  
17                 peals for the circuit in which the ultimate  
18                 parent entity of the ANDA filer or bio-  
19                 similar biological product application filer  
20                 is incorporated as of the date that the  
21                 ANDA or biosimilar biological product ap-  
22                 plication is filed with the Commissioner of  
23                 Food and Drugs.

24                  “(B) TREATMENT OF FINDINGS.—In a  
25                 proceeding for judicial review of a final order of

1           the Commission, the findings of the Commis-  
2           sion as to the facts, if supported by evidence,  
3           shall be conclusive.

4         “(e) ANTITRUST LAWS.—Nothing in this section  
5         shall modify, impair, limit, or supersede the applicability  
6         of the antitrust laws as defined in subsection (a) of the  
7         first section of the Clayton Act (15 U.S.C. 12(a)), and  
8         of section 5 of this Act to the extent that section 5 applies  
9         to unfair methods of competition. Nothing in this section  
10        shall modify, impair, limit, or supersede the right of an  
11        ANDA filer or biosimilar biological product application  
12        filer to assert claims or counterclaims against any person,  
13        under the antitrust laws or other laws relating to unfair  
14        competition.

15         “(f) PENALTIES.—

16           “(1) FORFEITURE.—Each party that violates or  
17           assists in the violation of this section shall forfeit  
18           and pay to the United States a civil penalty suffi-  
19           cient to deter violations of this section, but in no  
20           event greater than 3 times the value received by the  
21           party that is reasonably attributable to the violation  
22           of this section. If no such value has been received by  
23           the NDA holder, the biological product license hold-  
24           er, the ANDA filer, or the biosimilar biological prod-  
25           uct application filer, the penalty to the NDA holder,

1       the biological product license holder, the ANDA  
2       filer, or the biosimilar biological product application  
3       filer shall be sufficient to deter violations, but in no  
4       event shall be greater than 3 times the value given  
5       to an ANDA filer or biosimilar biological product  
6       application filer reasonably attributable to the viola-  
7       tion of this section. Such penalty shall accrue to the  
8       United States and may be recovered in a civil action  
9       brought by the Commission, in its own name by any  
10      of its attorneys designated by it for such purpose, in  
11      a district court of the United States against any  
12      party that violates this section. In such actions, the  
13      United States district courts are empowered to grant  
14      mandatory injunctions and such other and further  
15      equitable relief as they deem appropriate.

16       “(2) CEASE AND DESIST.—

17           “(A) IN GENERAL.—If the Commission has  
18       issued a cease and desist order with respect to  
19       a party in an administrative adjudicative pro-  
20       ceeding under the authority of subsection  
21       (a)(1), an action brought pursuant to para-  
22       graph (1) may be commenced against such  
23       party at any time before the expiration of 1  
24       year after such order becomes final pursuant to  
25       section 5(g).

1                 “(B) EXCEPTION.—In an action under  
2                 subparagraph (A), the findings of the Commis-  
3                 sion as to the material facts in the administra-  
4                 tive adjudicative proceeding with respect to the  
5                 violation of this section by a party shall be con-  
6                 clusive unless—

7                         “(i) the terms of such cease and de-  
8                 sist order expressly provide that the Com-  
9                 mission’s findings shall not be conclusive;  
10                 or

11                 “(ii) the order became final by reason  
12                 of section 5(g)(1), in which case such find-  
13                 ing shall be conclusive if supported by evi-  
14                 dence.

15                 “(3) CIVIL PENALTY.—In determining the  
16                 amount of the civil penalty described in this section,  
17                 the court shall take into account—

18                         “(A) the nature, circumstances, extent,  
19                 and gravity of the violation;

20                         “(B) with respect to the violator, the de-  
21                 gree of culpability, any history of violations, the  
22                 ability to pay, any effect on the ability to con-  
23                 tinue doing business, profits earned by the  
24                 NDA holder, the biological product license hold-  
25                 er, the ANDA filer, or the biosimilar biological

1           product application filer, compensation received  
2           by the ANDA filer or biosimilar biological prod-  
3           uct application filer, and the amount of com-  
4           merce affected; and

5                 “(C) other matters that justice requires.

6                 “(4) REMEDIES IN ADDITION.—Remedies pro-  
7                 vided in this subsection are in addition to, and not  
8                 in lieu of, any other remedy provided by Federal  
9                 law. Nothing in this paragraph shall be construed to  
10                 affect any authority of the Commission under any  
11                 other provision of law.

12                 “(g) DEFINITIONS.—In this section:

13                 “(1) AGREEMENT.—The term ‘agreement’  
14                 means anything that would constitute an agreement  
15                 under section 1 of the Sherman Act (15 U.S.C. 1)  
16                 or section 5 of this Act.

17                 “(2) AGREEMENT RESOLVING OR SETTLING A  
18                 PATENT INFRINGEMENT CLAIM.—The term ‘agree-  
19                 ment resolving or settling a patent infringement  
20                 claim’ includes any agreement that is entered into  
21                 within 30 days of the resolution or the settlement of  
22                 the claim, or any other agreement that is contingent  
23                 upon, provides a contingent condition for, or is oth-  
24                 erwise related to the resolution or settlement of the  
25                 claim.

1           “(3) ANDA.—The term ‘ANDA’ means an ab-  
2 breviated new drug application filed under section  
3 505(j) of the Federal Food, Drug, and Cosmetic Act  
4 (21 U.S.C. 355(j)) or a new drug application filed  
5 under section 505(b)(2) of the Federal Food, Drug,  
6 and Cosmetic Act (21 U.S.C. 355(b)(2)).

7           “(4) ANDA FILER.—The term ‘ANDA filer’  
8 means a party that owns or controls an ANDA filed  
9 with the Food and Drug Administration or has the  
10 exclusive rights under such ANDA to distribute the  
11 ANDA product.

12           “(5) ANDA PRODUCT.—The term ‘ANDA  
13 product’ means the product to be manufactured  
14 under the ANDA that is the subject of the patent  
15 infringement claim.

16           “(6) BIOLOGICAL PRODUCT.—The term ‘bio-  
17 logical product’ has the meaning given such term in  
18 section 351(i)(1) of the Public Health Service Act  
19 (42 U.S.C. 262(i)(1)).

20           “(7) BIOLOGICAL PRODUCT LICENSE APPLICA-  
21 TION.—The term ‘biological product license applica-  
22 tion’ means an application under section 351(a) of  
23 the Public Health Service Act (42 U.S.C. 262(a)).

1           “(8) BIOLOGICAL PRODUCT LICENSE HOLDER.—The term ‘biological product license holder’  
2           means—

3           “(A) the holder of an approved biological  
4           product license application for a biological prod-  
5           uct;

6           “(B) a person owning or controlling en-  
7           forcement of any patents that claim the biologi-  
8           cal product that is the subject of such approved  
9           application; or

10           “(C) the predecessors, subsidiaries, divi-  
11           sions, groups, and affiliates controlled by, con-  
12           trolling, or under common control with any of  
13           the entities described in subparagraphs (A) and  
14           (B) (such control to be presumed by direct or  
15           indirect share ownership of 50 percent or great-  
16           er), as well as the licensees, licensors, succee-  
17           sors, and assigns of each of the entities.

18           “(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The  
19           term ‘biosimilar biological product’ means the prod-  
20           uct to be manufactured under the biosimilar biologi-  
21           cal product application that is the subject of the pat-  
22           ent infringement claim.

23           “(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-  
24           CATION.—The term ‘biosimilar biological product ap-

1 plication' means an application under section 351(k)  
2 of the Public Health Service Act (42 U.S.C. 262(k))  
3 for licensure of a biological product as biosimilar to,  
4 or interchangeable with, a reference product.

5       **“(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-**  
6 **CATION FILER.**—The term ‘biosimilar biological  
7 product application filer’ means a party that owns or  
8 controls a biosimilar biological product application  
9 filed with the Food and Drug Administration or has  
10 the exclusive rights under such application to dis-  
11 tribute the biosimilar biological product.

12       **“(12) DRUG PRODUCT.**—The term ‘drug prod-  
13 uct’ has the meaning given such term in section  
14 314.3(b) of title 21, Code of Federal Regulations (or  
15 any successor regulation).

16       **“(13) MARKET.**—The term ‘market’ means the  
17 promotion, offering for sale, selling, or distribution  
18 of a drug product.

19       **“(14) NDA.**—The term ‘NDA’ means a new  
20 drug application filed under section 505(b) of the  
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22 355(b)).

23       **“(15) NDA HOLDER.**—The term ‘NDA holder’  
24 means—

1                 “(A) the holder of an approved NDA appli-  
2                 cation for a drug product;

3                 “(B) a person owning or controlling en-  
4                 forcement of the patent listed in the Approved  
5                 Drug Products With Therapeutic Equivalence  
6                 Evaluations (commonly known as the ‘FDA Or-  
7                 ange Book’) in connection with the NDA; or

8                 “(C) the predecessors, subsidiaries, divi-  
9                 sions, groups, and affiliates controlled by, con-  
10                 trolling, or under common control with any of  
11                 the entities described in subparagraphs (A) and  
12                 (B) (such control to be presumed by direct or  
13                 indirect share ownership of 50 percent or great-  
14                 er), as well as the licensees, licensors, succes-  
15                 sors, and assigns of each of the entities.

16                 “(16) PARTY.—The term ‘party’ means any  
17                 person, partnership, corporation, or other legal enti-  
18                 ty.

19                 “(17) PATENT INFRINGEMENT.—The term  
20                 ‘patent infringement’ means infringement of any  
21                 patent or of any filed patent application, including  
22                 any extension, reissue, renewal, division, continu-  
23                 ation, continuation in part, reexamination, patent  
24                 term restoration, patents of addition, and extensions  
25                 thereof.

1           “(18) PATENT INFRINGEMENT CLAIM.—The  
2 term ‘patent infringement claim’ means any allega-  
3 tion made to an ANDA filer or biosimilar biological  
4 product application filer, whether or not included in  
5 a complaint filed with a court of law, that its ANDA  
6 or ANDA product, or biosimilar biological product li-  
7 cense application or biosimilar biological product,  
8 may infringe any patent held by, or exclusively li-  
9 censed to, the NDA holder, biological product license  
10 holder, ANDA filer, or biosimilar biological product  
11 application filer of the drug product or biological  
12 product, as applicable.

13           “(19) STATUTORY EXCLUSIVITY.—The term  
14 ‘statutory exclusivity’ means those prohibitions on  
15 the approval of drug applications under clauses (ii)  
16 through (iv) of section 505(c)(3)(E) (5- and 3-year  
17 data exclusivity), section 527 (orphan drug exclu-  
18 sivity), or section 505A (pediatric exclusivity) of the  
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20 355(c)(3)(E), 360cc, 355a), or on the licensing of  
21 biological product applications under section  
22 351(k)(7) (12-year exclusivity) or paragraph (2) or  
23 (3) of section 351(m) (pediatric exclusivity) of the  
24 Public Health Service Act (42 U.S.C. 262) or under  
25 section 527 of the Federal Food, Drug, and Cos-

1       metic Act (21 U.S.C. 360cc) (orphan drug exclu-  
2       sivity).”.

3           (b) EFFECTIVE DATE.—Section 27 of the Federal  
4 Trade Commission Act, as added by this section, shall  
5 apply to all agreements described in section 27(a)(1) of  
6 that Act entered into on or after the date of enactment  
7 of this Act.

8 **SEC. 4. CERTIFICATION OF AGREEMENTS.**

9           (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)  
10 of the Medicare Prescription Drug, Improvement, and  
11 Modernization Act of 2003 (21 U.S.C. 355 note) is  
12 amended by inserting “, or the owner of a patent for which  
13 a claim of infringement could reasonably be asserted  
14 against any person for making, using, offering to sell, sell-  
15 ing, or importing into the United States a biological prod-  
16 uct that is the subject of a biosimilar biological product  
17 application” before the period at the end.

18           (b) CERTIFICATION OF AGREEMENTS.—Section 1112  
19 of the Medicare Prescription Drug, Improvement, and  
20 Modernization Act of 2003 (21 U.S.C. 355 note) is  
21 amended by adding at the end the following:

22           “(d) CERTIFICATION.—The Chief Executive Officer  
23 or the company official responsible for negotiating any  
24 agreement under subsection (a) or (b) that is required to  
25 be filed under subsection (c), within 30 days after such

1 filing, shall execute and file with the Assistant Attorney  
2 General and the Commission a certification as follows: ‘I  
3 declare that the following is true, correct, and complete  
4 to the best of my knowledge: The materials filed with the  
5 Federal Trade Commission and the Department of Justice  
6 under section 1112 of subtitle B of title XI of the Medi-  
7 care Prescription Drug, Improvement, and Modernization  
8 Act of 2003, with respect to the agreement referenced in  
9 this certification—’

10                 “(1) represent the complete, final, and exclusive  
11                 agreement between the parties;

12                 “(2) include any ancillary agreements that are  
13                 contingent upon, provide a contingent condition for,  
14                 or are otherwise related to, the referenced agree-  
15                 ment; and

16                 “(3) include written descriptions of any oral  
17                 agreements, representations, commitments, or prom-  
18                 ises between the parties that are responsive to sub-  
19                 section (a) or (b) of such section 1112 and have not  
20                 been reduced to writing.”.

21 **SEC. 5. NOTIFICATION OF AGREEMENTS.**

22                 Section 1112 of the Medicare Prescription Drug, Im-  
23                 provement, and Modernization Act of 2003 (21 U.S.C.  
24                 355 note), as amended by section 4(b), is further amended  
25                 by adding at the end the following:

1       “(e) RULE OF CONSTRUCTION.—

2           “(1) IN GENERAL.—An agreement that is re-  
3           quired under subsection (a) or (b) shall include  
4           agreements resolving any outstanding disputes, in-  
5           cluding agreements resolving or settling a Patent  
6           Trial and Appeal Board proceeding.

7           “(2) DEFINITION.—For purposes of subparagraph (A), the term ‘Patent Trial and Appeal Board proceeding’ means a proceeding conducted by the Patent Trial and Appeal Board of the United States Patent and Trademark Office, including an inter partes review instituted under chapter 31 of title 35, United States Code, a post-grant review instituted under chapter 32 of that title (including a proceeding instituted pursuant to the transitional program for covered business method patents, as described in section 18 of the Leahy-Smith America Invents Act (35 U.S.C. 321 note)), and a derivation proceeding instituted under section 135 of that title.”.

21   **SEC. 6. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

22       Section 505(j)(5)(D)(i)(V) of the Federal Food,  
23       Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))  
24       is amended by inserting “section 27 of the Federal Trade

1 Commission Act or” after “that the agreement has vio-  
2 lated”.

3 **SEC. 7. COMMISSION LITIGATION AUTHORITY.**

4 Section 16(a)(2) of the Federal Trade Commission  
5 Act (15 U.S.C. 56(a)(2)) is amended—

6 (1) in subparagraph (D), by striking “or” after  
7 the semicolon;

8 (2) in subparagraph (E)—

9 (A) by moving the margin 2 ems to the  
10 left; and

11 (B) by inserting “or” after the semicolon;

12 and

13 (3) inserting after subparagraph (E) the fol-  
14 lowing:

15 “(F) under section 27.”.

16 **SEC. 8. REPORT ON ADDITIONAL EXCLUSION.**

17 (a) IN GENERAL.—Not later than 1 year after the  
18 date of enactment of this Act, the Federal Trade Commis-  
19 sion shall submit to the Committee on the Judiciary of  
20 the Senate and the Committee on the Judiciary of the  
21 House of Representatives a recommendation, and the  
22 Commission’s basis for such recommendation, regarding  
23 a potential amendment to include in section 27(c) of the  
24 Federal Trade Commission Act (as added by section 3 of  
25 this Act) an additional exclusion for consideration granted

1 by an NDA holder to a ANDA filer or by a biological prod-  
2 uct license holder to a biosimilar biological product appli-  
3 cation filer as part of the resolution or settlement, a re-  
4 lease, waiver, or limitation of a claim for damages or other  
5 monetary relief.

6 (b) **DEFINITIONS.**—In this section, the terms  
7 “ANDA filer”, “biological product license holder”, “bio-  
8 similar biological product application filer”, and “NDA  
9 holder” have the meanings given such terms in section  
10 27(g) of the Federal Trade Commission Act (as added by  
11 section 3 of this Act).

12 **SEC. 9. STATUTE OF LIMITATIONS.**

13 The Federal Trade Commission shall commence any  
14 enforcement proceeding described in section 27 of the  
15 Federal Trade Commission Act, as added by section 3, ex-  
16 cept for an action described in section 27(f)(2) of the Fed-  
17 eral Trade Commission Act, not later than 6 years after  
18 the date on which the parties to the agreement file the  
19 certification under section 1112(d) of the Medicare Pre-  
20 scription Drug Improvement and Modernization Act of  
21 2003 (21 U.S.C. 355 note).

22 **SEC. 10. SEVERABILITY.**

23 If any provision of this Act, an amendment made by  
24 this Act, or the application of such provision or amend-  
25 ment to any person or circumstance is held to be unconsti-

1 tutional, the remainder of this Act, the amendments made  
2 by this Act, and the application of the provisions of such  
3 Act or amendments to any person or circumstance shall  
4 not be affected.

